

Applicant's Information Disclosure Statement filed with the present application. In the discussion below, references to Lerch DE are made to corresponding portions of the U.S. counterpart of Lerch rather than the German language reference.

Lerch DE was discussed in detail in Applicants' Amendment filed on April 7, 2008, which is incorporated herein by reference.

The Examiner indicates that Lerch DE discloses "*a bendable/flexible tension band (28) fixable on the outer abutment element*" (Office Action, page 2). Lerch DE discloses that the coupling element 28 is a thread or wire which is linearly flexible (Para. 0086). Applicants claim at least one elastically bendable tension band.

The Examiner also indicates that Lerch DE discloses "*hook elements (54/72) with an inclined/steep flank*" (Office Action, page 2). Reference numeral 54 of Lerch DE denotes a peg element on which the thread or wire 28 is wound around (Para. 0095). Further, reference numeral 72 of Lerch is a clamping seat which is formed as a fixing recess into which the thread or wire 28 can be clamped in order to fix the latter in relation to a second bearing element 66 (Para. 0097). In addition, it is evident from Figure 2 of Lerch DE that neither the peg element 54 nor the clamping recess 72 has an inclined steep flank and neither acts as any type of hook element. In addition, the use of a recess to fix a thread is directly contrary to the use of a hook element to fix a thread, so that Lerch DE can be seen to teach away from Applicants' claimed invention. In Lerch, the thread is clamped by the recess 72 so that the sides of the recess partially surround the thread, while with Applicants' claimed invention, the hook element penetrates the tension band so that the band surrounds the hook element.

Further, the Examiner states that Lerch DE discloses "*a dimension of the tension band is greater than another (thereby covering the width is greater than the height)*" (Office Action, page 2). Applicants respectfully submit that Lerch DE does not disclose or remotely suggest that the thread or wire 28 is provided with different width and height dimensions. In particular, Lerch DE does not disclose or remotely suggest that, at least in an area of the at least one tension band where the penetration occurs, a width of the at least one tension band is at least five times greater than the height of the at least one tension band, as claimed by Applicants. In contrast, in Lerch DE, the thread or wire 28 appears to be a length of circular material of constant diameter (or a

material where the width is substantially equal to the height). The Examiner apparently takes the overly broad position that since the thread or wire 28 of Lerch DE is quite long and very thin in relation to that length, it meets Applicants' claim limitation. Such a reading of Lerch DE ignores the fact that since Applicants' tension band has a height and width dimension, it inherently has a length dimension, as would be appreciated by those of ordinary skill in the art.

In view of the foregoing, the Examiner's conclusion that Lerch DE "*discloses all of the claimed limitations except for the spacing of the openings of the inner abutment plate being less than an eighth of a width dimension of the inner abutment element as well as hook elements disposed on the outer abutment element capable of penetrating through the tension band*" (Office Action, page 3) is incorrect.

As acknowledged by the Examiner, Lerch DE does not disclose or remotely suggest a hook element that can penetrate completely through the tension band for fixing the tension band relative to an outer abutment element, as claimed by Applicants. The Examiner asserts that Lerch US teaches "*hook members 223 disposed on the outer abutment element to grip bone in-between the inner and outer abutment elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the hook members as taught by Lerch ('631) to the device of Lerch et al ('359) in order to help grip the bone to which the elements are attached.*" (Office Action, page 3).

The Examiner is correct in that one skilled in the art would possibly have modified the bearing element 20 of Lerch DE with the teeth 223 of Lerch US to enable the fixing device to better grip the pieces of bone. However, Applicants respectfully submit that one skilled in the art would not have modified Lerch DE so as to provide the teeth 223 on the bearing element 20 in order to fix the wire or thread 28 to the bearing element 20 by penetration of the teeth 223 through the wire or thread 28.

There is simply no disclosure or suggestion that the teeth 223 of Lerch US are used to fix any type of tension band. In fact, the teeth 223 of Lerch US do not serve any function in fixing the two disks 21 and 22 in position on the bone plates. Rather, in Lerch US, the two disks 21 and 22 are fixed in their relative position via a shaft 112 which passes through the center of the disks 21 and 22 and is fastened to the disks using the type of tool used to fasten blind rivets. The tool

forces the outer disk 22 and the inner disk 21 together in a clamping direction until the teeth on each disk bite into the bone of the plug and the cranium, securing the two together (Col. 2, lines 54-66 and Col. 3, lines 32-36). Thus, the teeth 223 of Lerch US do not affect the shaft 112 in any manner and are not involved in moving the disks toward one another or securing them in position.

It is also noted that Applicants claim 1 specifies that the at least one tension band has a first free end and a second free end located above an outer surface of the outer abutment element, and that the one or more hook elements are associated with each of the first and second free ends for fixing the at least one tension band relative to the outer abutment element, with the one or more hook elements formed on the outer abutment element. Thus, since claim 1 specifies that the free ends are located above an outer surface of the outer abutment element, and that the hook elements are formed on the outer abutment element and associated with the free ends of the tension band, the hook elements are disposed on the outer surface of the outer abutment element. In contrast, Lerch US only discloses teeth 223 formed on an inner surface of the outer disk 22 for gripping bone tissue. There is no disclosure or suggestion in Lerch US of teeth disposed on an outer surface of the disk 22 for penetrating a tension band.

Further, it is respectfully submitted that one of ordinary skill in the art would have understood the purpose and function of teeth 223 of Lerch US to be to prevent transverse movement of the bone plug relative to the rest of the cranium, not to secure the two disks 21, 22 together.

There is no motivation for combining Lerch DE with Lerch US as indicated by the Examiner. It is noted that Lerch De and Lerch US share a common inventor, Karl-Dieter Lerch. Applicants respectfully submit that if it were obvious to combine these two references, such a combination would have been referenced by the common inventor on these references. Neither Lerch DE nor Lerch US reference any combination of the respective embodiments. If the common inventor listed on both references was not motivated to combine, then it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine their teachings as suggested by the Examiner.

Further, it is respectfully submitted that, even if one skilled in the art were somehow motivated to combine Lerch DE with Lerch US, one of ordinary skill in the art would appreciate that the embodiments shown in Figures 4-16 (using a rigid coupling element 76, 110, 130, etc. through the center of the bearing elements) of Lerch DE is closer in design to that of Lerch US (having a shaft 112 through the center of disks 21, 22 as a coupling element). Thus, it is respectfully submitted that one of ordinary skill in the art would more readily have modified the embodiments of Figures 4-16 of Lerch DE with features of Lerch US (rather than the Figure 1 embodiment of Lerch DE as indicated by the Examiner) to provide a fixing device having disks secured together with some type of a rigid coupling element passing through the center of the disks and where the disks have teeth for gripping the bone sections to be fixed. Such a device would not include an elastically bendable tension band which is fixed relative to the outer abutment element by hook elements that penetrate completely through the tension band, as claimed by Applicants.

It is respectfully submitted that, even in the event that one skilled in the art were somehow motivated to modify the Figure 1 embodiment of Lerch DE with the teeth 223 of Lerch US, one skilled in the art would also not have arrived at Applicants' claimed invention. Instead, one skilled in the art would have modified the inner and outer bearing elements 18 and 20 with teeth for gripping the bone tissue. One skilled in the art would not have modified Lerch DE with teeth for securing the thread or wire 28 since the securing means of Lerch DE appears to work fine for its intended purpose and there is no teaching in either reference of using teeth for securing a thread or wire.

Further, Lerch US does not cure the deficiencies of Lerch DE noted above. In particular, neither Lerch DE nor Lerch US discloses:

- an elastically bendable tension band;
- first and second free ends of a tension band disposed above an outer surface of an outer abutment element and secured thereto via hook elements which penetrate completely through the free ends of the tension band;
- a height of one or more hook elements being greater than a height of the at least one tension band; and

- a tension band having a width that is at least five times greater than its height, at least in the area where the hook element(s) penetrate the tension band.

Accordingly, the combination of Lerch DE and Lerch US would not lead to Applicants' claimed invention, as such a combination does not disclose or suggest at least the foregoing elements claimed by Applicants.

Applicants respectfully submit that the present invention would not have been obvious to one skilled in the art in view of Lerch DE in combination with Lerch US or any of the other prior art of record.

#### Discussion of Rejection based on Lerch DE in view of Golds

Independent claim 1 is rejected as being unpatentable over Lerch DE in view of Gold. The deficiencies of Lerch DE are discussed in detail above. Gold does not cure these noted deficiencies.

As discussed above, the Examiner acknowledges that Lerch DE does not disclose a hook element which completely penetrates through a tension band. The Examiner indicates that Gold teaches:

*a mechanism to gripping a tension band to prevent additional movement of the band in which it is located in the central opening of a device. It would have been obvious for one of ordinary skill in the art to substitute the means for gripping the flexible band in the device of Lerch ('359) with a hook element as taught by Golds et al to provide for a means of locking a tension band with predictable results. The hook element of Golds is inherently capable of penetrating through the flexible member should one desire.*

Office Action, page 4.

Golds discloses a strap assembly to be looped about split portions of human tissue to retain the split portions in adjacent contacting relation to promote healing. A strap 12 is provided which is looped through a buckle member 14. The buckle member 14 includes a frame 16 with a

clamp 18 mounted within the frame 16. Clamp 18 is adapted for rotation about axial pin 20 from an open position to permit passage of the strap 12 to a closed position securing the strap 12. The clamp 18 includes upper and lower wedging surfaces 32, 34, with teeth 40. Teeth 40 are angled to permit the strap to pass in one direction, i.e., a tensioning direction, while preventing it from passing in a loosening direction (Abstract, Col. 3, line 56 through Col. 5, line 3).

Golds is not directed towards an implant for fixing adjacent bone plates having an inner abutment element and an outer abutment element for overlapping a separation gap between the bone plates, as claimed by Applicants. It is respectfully submitted that Golds is far removed from Applicants' claimed invention and far removed from the device described in Lerch DE.

With Applicants' claimed invention, a height of the one or more hook elements is greater than a height of the at least one tension band. This feature enables the hook element(s) to penetrate completely through the tension band as claimed by Applicants. In contrast, it is readily apparent from Figure 4 of Golds that the teeth 40 are not of a height that is greater than a height of the strap 12 and do not penetrate completely through the strap 12.

Further, Golds teaches away from complete penetration of the teeth 40 through the strap 12, as when the clamp 18 is rotated into the closed position engaging the strap 12, the teeth 40 are angled so as to permit the strap to pass in a tightening direction to permit further tensioning of the strap 12, while preventing the strap from passing in an opposite loosening direction. If the teeth 40 of Golds penetrated completely through the strap, movement of the strap 12 would be prevented in each direction when the clamp 18 is rotated into the closed position.

Due to the disparate designs of Lerch DE and Golds, one skilled in the art would not be motivated to combine their teachings as indicated by the Examiner. For example, when securing adjacently arranged bone plates with a connecting element as in Lerch DE, there is no room for a rotating clamp mechanism 18 of the type used in Golds to be disposed between the two bearing elements 18 and 20, as is apparently suggested by the Examiner. Such an arrangement would create an unwanted gap between the adjacent bone plates being fixed together. Further, extensive modification would be required to make the clamp 18 of Golds work to secure the thread or wire 28 in the device of Lerch DE, such as enabling the clamp 18 for rotation between the two bearing elements 18 and 20 of Lerch DE, routing the thread or wire 28 so that it is somehow clamped by

the clamp 18 while still drawing the two bearing elements 18 and 20 together, and other design obstacles that would have been apparent to those skilled in the art.

Even in the event one skilled in the art was somehow motivated to combine the teachings of Lerch DE and Golds as suggested by the Examiner, such a device would be unworkable for the purpose intended in Lerch DE. Further, such a device based on the combination of Lerch DE and Golds (i.e., with a rotating clamp 18 disposed between the bearing elements 18 and 20 as suggested by the Examiner) would be far removed from Applicants' claimed invention, as would readily be apparent to one of ordinary skill in the art.

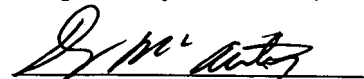
Further remarks regarding the asserted relationship between Applicants' claims and the prior art are not deemed necessary, in view of the foregoing discussion. Applicants' silence as to any of the Examiner's comments is not indicative of an acquiescence to the stated grounds of rejection.

Withdrawal of the rejections under 35 U.S.C. § 103(a) is therefore respectfully requested.

Conclusion

The Examiner is respectfully requested to reconsider this application, allow each of the pending claims and to pass this application on to an early issue. If there are any remaining issues that need to be addressed in order to place this application into condition for allowance, the Examiner is requested to telephone Applicants' undersigned attorney.

Respectfully submitted,



Douglas M. McAllister  
Attorney for Applicant(s)  
Registration No.: 37,886  
Lipsitz & McAllister, LLC  
755 Main Street  
Monroe, CT 06468  
(203) 459-0200